GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2528
ANSWERED ON:31.07.2002
CLINICAL TRIALS
BIJOY KRISHNA HANDIQUE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government propose to amend provisions governing clinical trials of new drugs to allow such trials to take place in India simultaneously with trials in the country of origin of the new drugs; and

(b) if so, the details thereof and the reasons therefor?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) Current provisions of Schedule `Y` of Drugs and Cosmetics Rules are not conducive to growth of clinical research as they hamper collaborative research and concomitants multicentric clinical trials. Thus at various scientific fora the need has been expressed for updating the provisions of Schedule `Y` to have international acceptance of regulations governing clinical trials.

The matter was deliberated by the Drugs Technical Advisory Board (DTAB).It was decided that the proposal to revise Schedule `Y` may be considered by an Expert Committee. The detailed deliberations and review of the existing Schedule `Y` is in progress by experts and ICMR.